K131901

Section 6: 510(k) SUMMARY

DEC 2 3 2013

[As required by 21 CFR §807.92(c)]

Date Prepared: June 12, 2013

Official Contact:

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Device Trade Name: iVolve® Nasal Mask
iVolve® Full Face Mask
iVolve® N2

Device Common Name: Nasal Mask, Full Face Mask

Classification Name: Vented Nasal Mask

Classification: 21 CFR §868.5905, 73 BZD (CLASS II)

Product Code: BZD

Predicate Devices:

Manufacturer:	Resmed
Trade Name:	Mirage Activa LT Nasal Mask
510(k) Number:	K030798

Manufacturer:	Resmed
Trade Name:	Mirage Quattro Full Face Mask
510(k) Number:	K113127

Manufacturer:	BMC
Trade Name:	Willow Nasal Mask
510(k) Number:	K112271

Device Description:

The iVolve® N2 and Nasal Masks are respiratory nasal mask interfaces that directs airflow from a positive pressure device to the patient's nose. The iVolve® Full-Face Mask is a mask interface that directs air flow from a positive pressure device to the patient's nose or mouth. The iVolve® Mask Series is held in place with adjustable headgear that straps the mask to the face.

The iVolve® is safe when used under the conditions and purposes intended as indicated the labeling provided with the product.

The iVolve® is a prescription device supplied non-sterile.

Intended Use:

The iVolve® Mask channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or Bi-level system.
The iVolve® Mask is:
1. to be used by adult patients (>66lb/30 kg) for whom positive airway pressure has been prescribed.
2. intended for single-patient re-use in the home, hospital, and sub-acute environment.

Contraindications: None

Clinical Test: None

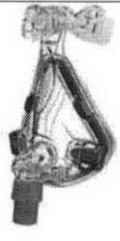
Technological Characteristics Comparison:

A comparative table of the iVolve® alongside the three identified predicate devices indicates that the iVolve Mask Series is substantially equivalent with the other three with respect to the form, performance, materials, structures and the ventilation characteristics.

The iVolve mask series, including the iVolve Nasal, iVolve Full Face, and iVolve N2, are identical to the identified predicate Willow device in material composition (i.e. silicone, molded plastic, and nylon fabric). Both the proposed devices and the predicate devices connect to a conventional air delivery hose between the mask and the positive airway pressure source via standard conical connectors (ISO 5356-1-2004).

Both the proposed devices (the iVolve Mask Series) and the predicate devices have similar technical performance characteristics, including pressure-flow characteristics and flow impedance.

SE Table

Manufacture	**BMC**	**RESmed**	**RESmed**	**BMC**
Model	**iVolve® Nasal Mask**	**Mirage™ Activa LT Nasal Mask (K030798)**	**Mirage™ Quattro Full Face Mask (K113127)**	**Willow Nasal Mask (K112271)**
Picture				

Intended use				
	The iVolve® channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or Bi-level system. The iVolve® is: • To be used by adult patients (>30 kg) for whom positive airway pressure has been prescribed. • Intended for single-patient re-use in the home environment. • Intended for prescription use only.	Mirage Activa™ mask is an accessory to a non-continuous ventilator (respirator) intended for single-patient use for adult patients prescribed continuous positive airway pressure (CPAP) and bi-level therapy in hospital, clinic, and home environments.	The Mirage™ Quattro Full Face Mask channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system. The Mirage™ Quattro is to be used by adult patients (>66lb/ >30kg) for whom positive airway pressure has been prescribed. The Mirage™ Quattro is intended for single patient re-use in the home environment and/or hospital/ institutional environment.	The Willow™ channels airflow noninvasively to a patient from a positive airway pressure (PAP) device or a bilevel system. The WillowTM is: (1) to be used by adult patients (> 661b / 30 kg) for the treatment of sleep disordered breathing, such as obstructive sleep apnea (OSA), for whom positive airway pressure has been prescribed. (2) to be used for single-patient reuse in the home environment.
Construction				
Nasal	Yes	Yes	Yes	Nasal pillows
Dual-wall Cushion	Yes	Yes	Yes	
Adjustable Forehead Support	Yes	Yes	Yes	

With Headgear	**Yes**	**Yes**	**Yes**	**Yes**
With Clips	**Yes**	**Yes**	**Yes**	
Multi Size	**Yes**	**Yes**	**Yes**	**Yes**
Dead Space – (empty volume of the mask to the end of the swivel)	**Nasal Mask** **S: 123.6ml** **M: 134ml** **L: 145 ml** **Full-Face Mask** **S: 220ml** **M: 232ml** **L: 246ml** **N2 Mask** **S:123.6ml** **M: 129ml** **L: 134.1ml**	**S: 123.3ml** **M: 134.1ml** **L: 145.2ml**	**S: 217ml** **M: 228ml** **L: 243ml**	
Chemical Characteristics				
Cushion	**Silicone**	**Silicone**	**Silicone**	**Silicone**
Headgear	**stretch nylon**	**stretch nylon**	**stretch nylon**	**stretch nylon**
Specification				
Therapy Pressure	**4-30cmH2O**	**4-20 cmH2O**	**4-20 cmH2O**	**4-20 cmH2O**
connector	**22mm**	**22mm**	**22mm**	**22mm**
Resistance/Pressure Drop **iVolve Nasal Mask** **iVolve Full Face Mask**	**0.2 cmH2O at 50L/min** **0.7 cmH2O at 100L/min** **0.1 cm H2O at 50L/min** **0.5 cm H2O at 100L/min** **0.2 cm H2O at**	**0.4 cmH2O at 50L/min** **0.9 cmH2O at 100L/min** **----------** **0.4 cm H2O at 50ml/min**	**----------** **0.2 cmH2O at 50L/min** **0.4 cmH2O at 100L/min** **----------**	**1.0 cmH2O at 50L/min** **3.1 cmH2O at 100L/min**

iVolve N2	50L/min 0.5 cm H2O at 100L/min	0.9 cm H2O at 100ml/min		
Operating and Storage Conditions				
Operating	+5 to +40°C 15% to 93% relative humidity, non-condensing	+5 to +40°C 15% to 95% relative humidity, non-condensing	-41 to 104°F(+5 to +40°C) 15% to 95% relative humidity, non-condensing	+5°C to +40°C 10%–93 % relative humidity non-condensing
Storage	-20 to +55°C 10% to 93% relative humidity, non-condensing	-20 to +60°C up to 95% relative humidity, non-condensing	-4 to 140°F(-20 to +60°C) 15% to 95% relative humidity, non-condensing	- 20°C to + 55°C 10%–93 % relative humidity non-condensing

Non-Clinical Performance Data:

The materials used in the iVolve series are identical to those used in the predicate Willow mask and have undergone and passed biocompatibility testing in accordance with ISO 10993: cytotoxicity, animal skin irritation, implantation, genotoxicity, and Kligman maximization.

Home Cleaning Validation Testing confirms that the iVolve mask series can withstand 200 cycles of cleaning and assessment for degradation of materials, including simulated use.

Both the proposed devices and the predicate devices have similar performance characteristics as shown in the substantial equivalence table. Performance bench testing of the proposed iVolve Mask Series did not raise any new questions of safety

and efficacy.

The iVolve was performance bench tested against the ResMed Mirage Activa (K030798) and the ResMed Mirage Quattro (K113127). As the tables below show, in terms of performance characteristics (i.e. passive exhalation port flow, resistance to flow, and dead space), the two devices are substantially equivalent.

iVolve Nasal Mask					
Name of Test	**Reason for Test**	**Size Tested**	**No. Samples Tested**	**Objective**	**Result/Conclusion**
Flow/Pressure Curve	to determine the flow/pressure curve at pressures 4, 8, 12, 16, 20, 25, 30 cmH2O	M*	3	a) to meet intended product specifications; b) to compare to range of predicate ±15%	within limits/pass
Pressure Drop/Resistance	to determine the pressure drop/resistance to flow at 50, 100L/min.	M*	3	a) to meet intended product specifications; b) to compare to range of predicate ±15%	within limits/pass
Dead Space	to determine the dead space for each size	s,m,l	3	a) to meet intended product specifications; b) to compare to range of predicate ±15%	within limits/pass

iVolve N2 Nasal Mask

Name of Test	Reason for Test	Size Tested	No. Samples Tested	Objective	Result/Conclusion
Flow/Pressure Curve	to determine the pressure drop/resistance to flow at 50, 100L/min.	M*	3	a) to meet intended product specifications; b) to compare to range of predicate ±15%	within limits/pass
Pressure Drop/Resistance	to determine the pressure drop/resistance to flow at 50, 100L/min.	M*	3	a) to meet intended product specifications; b) to compare to range of predicate ±15%	within limits/pass
Dead Space	to determine the dead space for each size	s,m,l	3	a) to meet intended product specifications; b) to compare to range of predicate ±15%	within limits/pass

iVolve Full-Face Mask					
Name of Test	**Reason for Test**	**Size Tested**	**No. Samples Tested**	**Objective**	**Result/Conclusion**
Flow/Pressure Curve	to determine the flow/pressure curve at pressures 4, 8, 12, 16, 20, 25, 30 cmH2O	M*	3	a) to meet intended product specifications; b) to compare to range of predicate ±15%	within limits/pass

Pressure Drop/Resistance	to determine the pressure drop/resistance to flow at 50, 100L/min.	M*	3	a) to meet intended product specifications; b) to compare to range of predicate ±15%	within limits/pass
Dead Space	to determine the dead space for each size	s,m,l	3	a) to meet intended product specifications; b) to compare to range of predicate ±15%	within limits/pass

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 23, 2013

3B Medical, Incorporated
Mr. Alex Lucio
Vice President
21301 Highway 27N
Lake Wales, FL 33859

Re: K131901
Trade/Device Name: iVolve Nasal Mask, iVolve Full Face Mask, iVolve N2
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: November 15, 2013
Received: November 19, 2013

Dear Mr. Lucio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

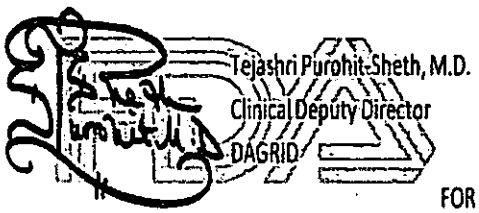
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K131901

Device Name
iVolve Mask Series

Indications for Use *(Describe)*

The iVolve® Mask channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or Bi-level system.
The iVolve® Mask is:
1. to be used by adult patients (>66lb/30 kg) for whom positive airway pressure has been prescribed.
2. intended for single-patient re-use in the home, hospital, and sub-acute environment

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anya C. Harry -S
2013.12.23 11:46:31 -05'00'

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